

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

DMB

Display Date 10-24-03  
Publication Date 10-27-03  
Certifier A. Corbin

[Docket No. 1999D-1938]

**Review and Revision of Guidances for Industry on the Development of  
Generic Drug Products; Development and Use of Food and Drug  
Administration Guidance Documents; Update and Withdrawal of Guidances**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; update and withdrawal of guidances.

---

**SUMMARY:** The Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), Office of Generic Drugs (OGD) is updating drug manufacturers on OGD efforts to review policy and procedure guides (PPGs) and other existing OGD documents that provide guidance on the development of generic drug products. We are also announcing the withdrawal of a list of PPGs that have become obsolete or have been replaced with other guidances or agency directives (manuals for policy and procedures (MaPPs)).

**DATES:** General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Copies of agency guidance documents can be obtained on the Internet at <http://www.fda.gov/cder/guidance/index.htm>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Rita R. Hassall, CDER (HFD-600), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-5845.

cd0394

N/

**SUPPLEMENTARY INFORMATION:** Since the early 1990s, OGD has developed and issued more than 40 PPGs to provide information to industry on the development of generic drug products and to set forth procedures for the review of generic drug applications. In addition, other guidance has been provided in the form of letters and other communications to industry.

On July 8, 1999, the agency announced in the **Federal Register** (64 FR 36886) a long-term effort to review all of its guidances and identify those that need to be revised, those that need to be reformatted for consistency with the agency's good guidance practices regulation (GGP) (21 CFR 10.115), and those that need to be withdrawn because they are no longer current. As an initial step in that process, OGD withdrew a number of drug-specific bioequivalence guidances and a number of labeling guidances that were outdated and no longer reflected the current thinking of the agency.

This notice has a twofold purpose: (1) It updates manufacturers on the status of OGD efforts to review existing guidances, and (2) it announces the withdrawal of 30 PPGs that are obsolete.

The PPGs that are being withdrawn are listed below. In each case, the reason for the withdrawal has been provided in parentheses.

- 1–89 “Correspondence Practices” (The guidance “Major, Minor, and Telephone Amendments to Abbreviated New Drug Applications” describes current correspondence practices.)
- 3–89 “Handling Telephone Inquiries on Status of Processing from Applicants or Their Representatives” (MAPP 5020.1 has been issued on this topic.)
- 4–89 “Microbiology Consults” (It is no longer needed as OGD has its own microbiology staff.)

- 6–89 “Not Approvable Actions for ANDA<sup>1</sup> and AADA<sup>2</sup> Supplements” (The guidance “Major, Minor, and Telephone Amendments to Abbreviated New Drug Applications” describes current correspondence practices.)
- 8–89 “Changes in the Labeling of ANDAs Subsequent to Revision of Innovator Labeling” (The guidance “Revising ANDA Labeling Following Revision of the RLD<sup>3</sup> Labeling” addresses this topic.)
- 9–89 “Delivery of Documents to the Office of Generic Drug’s Document Room; Providing Requested Documents to Messengers and Other Representatives of ANDA/AADA Applicants” (This describes interactions with messengers and other representatives that have been overtaken by advances in technology. See also guidance “Major, Minor, and Telephone Amendments to Abbreviated New Drug Applications” for information on current correspondence practices.)
- 10–89 “Meetings With Pharmaceutical Firm Employees or Their Representatives” (This is addressed in CDER MAPP 4512.1.)
- 11–89 “Shredding of Carbons and Draft Reviews and Letters” (This has been overtaken by advances in technology.)
- 12–89 “Number of Manufacturing Sites Permitted in an ANDA or AADA” (This was superceded by the guidance “Variations in Drug Products that May Be Included in a Single ANDA.”)
- 13–89 “Testing Requirements Applicable to Finished Dosage Forms Manufactured Outside the United States” (This material will be incorporated into the center’s guidance on “Stability Testing of Drug Substances and Drug Products,” which issued as a draft in June 1998.)

---

<sup>1</sup> ANDA means Abbreviated New Drug Application.

<sup>2</sup> AADA means Abbreviated Antibiotic Drug Application.

<sup>3</sup> RLD means Reference Listed Drug.

- 14–89 “Signatory Concurrence and Agreement on Final Typed Reviews and Letters and Other Items in the Administrative File” (This is addressed by MaPP 4151.1.)

- 16–90 First in-First Reviewed Policies” (This was superseded by PPG 38–93, then addressed by MaPP 5240.3.)

- 18–90 “Requests for Expedited Review of Supplements to Approved ANDAs and AADAs” (This became MaPP 5240.1.)

- 19–90 “Availability of Labeling Guidance” (This became MaPP 5230.1.)

- 20–90 “Variations in Solid Oral Dosage Forms and Injectables That Can Be Included Within a Single ANDA” (The guidance “Variations in Drug Products that May be Included in a Single ANDA” was issued on this topic.)

- 21–90 “First In-First Reviewed Policy and Exceptions Applied to Supplemental Applications” (This was superseded by PPG 38–93, then addressed by MaPP 5240.3.)

- 24–90 “Improvement by the Applicant of Unreviewed Original ANDA and AADA Submissions” (This is no longer needed given existence of form OGD uses to receive applications. See “ANDA Checklist for Completeness and Acceptability of an Application,” [http://www.fda.gov/cder/ogd/anda\\_\\_checklist.doc](http://www.fda.gov/cder/ogd/anda__checklist.doc).)

- 25–90 “Removal of Work-Related Materials from the Division at the End of Employment” (This is covered by existing CDER exit policies.)

- 26–90 “Reference to Type I DMF’s <sup>4</sup> in ANDAs and AADAs” (This is obsolete as type I DMFs are no longer used.)

- 27–90 “Acceptance for Filing and Review of AADAs Absent Approval of the Referenced Bulk Antibiotic” (This became MaPP 5240.2; the MaPP was

---

<sup>4</sup>DMF means Drug Master Files.

then withdrawn with repeal of section 507 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 357).)

- 30–91 “Organization of an ANDA and an AADA” (This is addressed in the guidance for industry “Organization of an ANDA.”)
- 32–92 “Reaffirmation of Expiration Dating Period for Abbreviated Applications” (This is addressed by MaPP 5226.1.)
- 33–92 “Consistent Container Information in an Abbreviated Application” (This is addressed by MaPP 5225.2.)
- 34–92 “Implementation of the Fraud, Untrue Statements of Material Facts, Bribery and Illegal Gratuities Final Policy” (Revised October 3, 1992 (An agency-level policy addresses this topic.)
- 35–92 “Revision of Exhibit Batch Requirements for Abbreviated Antibiotic Drug Applications” (This became MaPP 5223.1; the MaPP was then withdrawn with repeal of section 507 of the act.)
- 36–92 “Submission of an Investigational New Drug Application to the Office of Generic Drugs” (This is addressed by MaPP 5240.4.)
- 37–92 “Management of Office and Center Committees” (This was previously withdrawn per memo dated February 14, 1997, because of center committee reorganization.)
- 38–93 “Restatement of the Office of Generic Drugs First In-First Reviewed Policy and Modifications of the Exceptions to the Policy Regarding Minor Amendments” (This is addressed by MaPP 5240.3.)
- 40–94 “Scoring Configuration of Generic Drug Products” (This is addressed by MaPP 5223.2.)
- 41–95 “Packaging of Test Batches” (This is addressed by MaPP 5225.1.)

A number of other PPGs and other OGD documents are undergoing revision. Some of them will be issued as MaPPs; others will be revised and

reissued in the form of guidances for industry consistent with the GGP regulation.


The agency welcomes public comment on its efforts to review existing guidances related to the development of generic drugs and revise, reformat, or withdraw them as appropriate. The agency is also requesting public comment on topics for future guidance development regarding generic drugs.

This information is being issued consistent with FDA's GGPs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written comments. Two copies of any mailed comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this

document. Received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 10/14/03  
October 14, 2003.

  
\_\_\_\_\_  
Jeffrey Shuren,  
Assistant Commissioner for Policy.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

**BILLING CODE 4160-01-S**

COPIED TO 2127  
COPY OF THE ORIGINAL  
